DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2014

Easymed Instruments Co., Ltd
Mr. Jeffery Wu (Wu Tingjie)
General Manager
5/F – 6/F, Block A, Gupo Gongmao Building, Fengxin Road,
Fengxiang Industrial District, Daliang, 528300 Shunde, Foshan,
Guangdong, CHINA

Re: K140168
Trade/Device Name: EasyStim TN28_OTC
Regulation Number: 21 CFR 882.5890
Regulation Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter
Regulatory Class: Class II
Product Code: NUH
Dated: May 22, 2014
Received: June 02, 2014

Dear Mr. Tingjie Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140168

Device Name
EasyStim TN28_OTC

Indications for Use *(Describe)*
EasyStim TN28_OTC is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.08.28 17:19:10 -04'00'

510(k) Summary

Date of submission prepared: 5th December 2013

Submitter: EasyMed Instruments Co., Ltd.
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Tel : +86 757 2809 1300
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E-Mail : jeffery@easymed.com.cn

Official Contact: Jeffery Wu (Wu Tingjie)

Address of the manufacturing facility: The same as above

SUBMITTED DEVICE:

Generic Name: Transcutaneous Electrical Nerve Stimulator (T.E.N.S.)

Proprietary or Trade Name: EasyStim TN28_OTC

Common/Usual Name: Stimulator, nerve, transcutaneous, over-the-counter

Classification Name: Stimulator, nerve, transcutaneous, over-the-counter
21 CFR 882.5890

Product Code: NUH

Device Panel: Neurology

Device Classification: Class II

PREDICATE DEVICES:

Device Name: Model PM3030
Manufacturer: Omron Healthcare, Inc.
510(k) Number: K110068
Product Code: NUH

Add: 5/F-6/F, Gupo Gongmao Building, Fengxin Road, Fengxiang Industrial District, Da Liang, 528300 ShunDe, GuangDong, China
Tel: 86-757-28091300 Fax：86-757-27727868

Device Name: EasyMed TN-28C T.E.N.S. Unit
Manufacturer: EasyMed Instrument Co., Ltd
510(k) Number: K040253
Product Code: GZJ

INDICATIONS FOR USE:

This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.

DEVICE DESCRIPTION:

EasyStim TN28_OTC is a portable, battery powered T.E.N.S. device for pain relief intended for over-the-counter use.

There are totally eight (8) modes that are intended for application to the following areas: Shoulder/ Arm, Lower Back and Leg/Foot.

The accessories include electrode cable and electrodes pads which are placed on the specific body part. Generally, the electrodes are connected to the device through electrode cable. The device produces either a fixed or modulated electrical signal through electrodes normally placed on a patient's skin over the area of pain.

Since the device is battery powered, there is no connection to AC mains supply.

ENVIRONMENT OF USE: Clinics, hospital and home environments

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SUMMARY OF SUBSTANTIAL EQUIVALENCE

Attribute	**New Device**	**Predicate Device (1)**	**Predicate Device (2)**
Product Name	EasyStim TN28_OTC	Model PM3030	EasyMed TN-28C T.E.N.S. Unit
510(K) number	(to be assigned)	K110068	K040253
Product Code	NUH	NUH	GZJ
Regulation No.	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890
Indications for Use	This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.	This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.	This T.E.N.S. system is used to provide symptomatic pain relief for chronic, acute or post operative pain.
Patient Population	Adult	Adult	Not specified
Prescriptive or OTC	OTC	OTC	Prescription
Environment of use	Clinics, hospital and home environments	Clinics, hospital and home environments	Not specified
Number of output modes	8	3	5
Number of output channels	2	1	2
Waveform	Biphasic rectangular Monophasic rectangular	Biphasic rectangular Monophasic rectangular	Symmetrical Bi-phasic rectangular Asymmetrical Bi-phasic rectangular Monophasic rectangular
Maximum Output Voltage(max) 500 ohm 2k ohm 10k ohm	 68V 102V 110V	 35.6V 46.4V 50.4V	 74.4V 109V 116V
Maximum Output Current(max) 500 ohm 2k ohm	 133mA 51mA 11mA	 69.8mA 23.2mA	 145mA 54.5mA 11.6mA

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10k ohm		5.04mA	
Maximum Phase charge (500 ohm)	20.02μC	7.12μC	21.62μC
Maximum Average Current (500 ohm)	3.0375mA	0.528mA	3.243mA
Maximum Current Density (500 ohm)	0.188mA/cm^2	0.0084mA/cm^2	0.20mA/cm^2
Maximum Average Power Density (500 ohm)	7.52mW/ cm^2	0.202mW/cm^2	8.764mW/cm^2
Frequency (Hz)	From 1Hz to 150Hz	From 1Hz to 110 Hz	From 1Hz to 150Hz Adjustable
Pulse Duration (μs)	50-250μs, in steps of 50μs	1-100μs	50-250μs, in steps of 50μs
Burst Mode	Yes	None	Yes
Timer range(min)	20min, 25min, 30min, 40min depending on preset program	15 minutes for all programs	Continuous, 15min, 30min, 45min, 60min, 90min selectable
Indication display -On/Off status -Low battery -Voltage/Current level -Output mode -Time to cut-off	 Yes Yes Yes Yes Yes	 Yes No Yes Yes No	 Yes Yes Yes Yes Yes
Power Source	2 Alkaline AA 1.5V (LR6) Batteries	2 AAA Batteries	2 Alkaline AA 1.5V (LR6) Batteries
Dimensions (mm)	66×136×30.7	55 x95 x 19	66×136×30.7
Weight	146.5 grams	60 grams	146.5 grams
Housing material	ABS	ABS	ABS
Microprocessor control	Yes	Yes	Yes
Automatic Overload trip	Yes	Yes	Yes
Automatic no-load trip	Yes	Yes	Yes
Automatic shut-off	Yes	Yes	Yes
User override control	Yes	Power On/Off button	Yes
Electrode compliance with 21 CFR 898	Yes	Yes	Yes
Electrode cable	Yes	Yes	Yes

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DIFFERENCES BETWEEN NEW DEVICE AND PREDICATE DEVICES

The technical characteristics of EasyStim TN28_OTC are similar to those of the predicate devices in design, energy source, intended use and function. Like the predicate device Model PM3030 (K110068) and EasyMed TN-28C T.E.N.S. Unit (K040253), the EasyStim TN28_OTC is a device used to apply an electrical current to electrodes on a patient's skin to relieve pain.

The stimulation parameters of new device EasyStim TN28_OTC are all in the same range of those of predicate device TN-28C(K040253) and similar to those of Model PM3030 (K110068). Furthermore, the designed circuitry of new device EasyStim TN28_OTC is very similar to the marketed device TN-28C (K040253), they are of similar circuit diagrams, similar working principle, and same plastic housing.

Some output characteristics of EasyStim TN28_OTC are different from those of Model PM3030 (K110068). However, the maximum phase charge (the charge delivered per pulse) of EasyStim TN28_OTC is 20.02μC, which is less than 25μC. On the other hand, the maximum average power density of EasyStim TN28_OTC is 0.00752W/cm^2, which is also less than 0.25W/cm^2. Furthermore, the frequency range of EasyStim TN28_OTC is from 1Hz to 150Hz, which is same as TN-28C(K040253) but different from Model PM3030 (K110068). But it needs 20 steps to reach up to the maximum output frequency (150Hz). Therefore, the differences between EasyStim TN28_OTC and Model PM3030 (K110068) are insignificant in terms of safety.

The EasyStim TN28_OTC is viewed as substantially equivalent to the predicate devices because: the electrical stimulation provided by the EasyStim TN28_OTC is substantially equivalent to that commonly employed by TENS devices that have been cleared for marketing without prescription labeling, i.e. for OTC use. The pulses in the waveform combinations are restricted in amplitude and duration to values consistent with other cleared devices.

Technological characteristics, features, specifications, materials and intended uses of the EasyStim TN28_OTC are substantially equivalent to the predicate devices. The differences that exist between EasyStim TN28_OTC and predicate devices are insignificant in the terms of safety or effectiveness.

PERFORMANCE TESTS: The relevant standards including:
AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012,, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, Mod). (General I (QS/RM))

IEC 60601-1-2 Medical Electrical Equipment-Part 1-2: General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility- Requirements and Tests(Ed.3) (General)

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IEC 60601-1-11 (Edition1.0 2010-04), Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment [Including: Technical Corrigendum 1(2011)]. (General I (QS/RM))

IEC 60601-1-6 Medical Electrical Equipment-Part 1-6: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Usability: 2010

IEC 62304 ED.1.0, Medical devices software- Software life cycle processes (Software/ Informatics)

ISO 14971: Medical devices- Application of risk management to medical devices. (General)

IEC 60601-2-10 Edition 2.0 2012-06, Medical Electrical Equipment -- Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators. (Neurology)

USABILITY STUDY:

A usability study was conducted and showed that users were able to use the device correctly and safety.

CONCLUSION:

The new device EasyStim TN28_OTC has the same indications for use and similar technological characteristics as the predicate devices Model PM3030 (K110068) and TN-28C (K040253). The stimulation parameters of new device EasyStim TN28_OTC are all in the same range of those of predicate devices. Thus, the new device EasyStim TN28_OTC is substantially equivalent to the predicate devices and any differences between the devices do not pose any new questions of safety and effectiveness.

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